

06-18-03

1636

CASE 4-31499A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV33554158845

Express Mail Label Number

June 17, 2003

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#15

IN RE APPLICATION OF

Art Unit: 1636

BUEHLER ET AL.

APPLICATION NO: 09/899,634

FILED: JULY 5, 2001

FOR: PCAR AND ITS USES

RECEIVED

JUN 20 2003

TECH CENTER 1600/2900

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action mailed May 20, 2003.

The Examiner has indicated that the claimed subject matter is drawn to four distinct inventions and has required restriction to one of the following inventions, Group I: Claims 1 and 2 classified in class 530, subclass 350, drawn to a C-terminally truncated porcine CAR protein or fragment or variant thereof; Group II: Claims 3-10 classified in class 536, subclass 23.5, drawn to a DNA sequence encoding the C-terminally truncated porcine CAR of Group I and a vector and host cell comprising the DNA sequence, Group III: Claims 11-14 and 16-23 classified in class 800, subclass 8, drawn to a transgenic rodent or pig and method of making the transgenic rodent or pig; and Group IV: Claims 15, 24 and 25 classified in class 800, subclass 3, drawn to a method for testing adenoviral transduction of an adenoviral gene delivery vector. Applicants provisionally elect, with traverse, to prosecute the invention of Group II: Claims 3-10.

35 U.S.C. § 121 maintains that for a proper requirement for restriction, the dual criteria of the statute must be met, that is, the application must contain two or more inventions which are both (1) "independent" and (2) "distinct" from one another. According to the U.S. Patent and Trademark Office's own definition, "independent" means "there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected in design, operation or effect..." (Section 802.01 of the Manual of Patent Examining Procedure). The specification of the present application discloses a relationship and connection between the Claims of Group II and Groups I, III and IV. In particular, the DNA sequence as recited in Claim 3 of Group II is

required in the method of generating the transgenic rodent or pig as recited in Claims 11-14 and 16-23 of Group III and in the method of testing adenoviral transduction of an adenoviral gene delivery vector as recited in Claims 15, 24 and 25 of Group IV. Additionally, the DNA sequence of Claim 3 is the sequence encoding the C-terminally truncated porcine CAR protein recited in Claims 1 and 2 of Group I. Accordingly, there is a relationship and connection between the Claims of Group II and the Claims of Groups I, III and IV, i.e., each requires the DNA sequence encoding the C-terminally truncated porcine CAR. Accordingly, the requirement for restriction and election is unwarranted under 35 U.S.C. §121 which, in order to authorize restriction, requires that the application claim "two or more independent and distinct inventions".

As a second ground for traversal, Applicants submit that the examiner has failed to show that there would be a "serious burden" upon the Patent and Trademark Office to examine all of the pending claims. In this regard, MPEP §803, second paragraph, states:

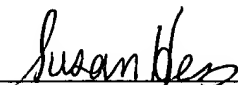
"There must be a serious burden on the examiner if restriction is required."

It is respectfully submitted that since the Claims in Groups I, II, III and IV require the DNA sequence which encodes a C-terminally truncated porcine CAR, that a search and examination of Groups I, III, IV would substantially overlap with a search and examination of Group II and therefore would not impose a "serious burden" on the Examiner. In view of the above, withdrawal of the Restriction Requirement is respectfully requested. Applicants retain the right to petition from the Restriction Requirement under 37 C.F.R. §1.144.

Early and favorable action are respectfully requested.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080  
(862) 778-7859

  
\_\_\_\_\_  
Susan Hess  
Attorney for Applicants  
Reg. No. 37,350

Date: June 17, 2003